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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,137	JOOS ET AL.	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 November 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *23-27* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22 and 28-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-22 and 28-39 in the reply filed on 01 November 2004 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-22 and 28-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. In claim 1, line 2, the phrase "using a second physicochemical property" is vague and indefinite. The specification does not define the phrase and it is unclear how the second physicochemical property is being used.

5. In claim 1, lines 4 and 6, the phrase "the composition of the respective compound is vague and indefinite. Lines 1-2 of the instant claim recite "two compounds". However, it unclear clear if the instant phrase refers to one of the two compounds or to another compound.

6. In claim 1, lines 1-7, the phrase "A method for determining...comprising the steps of:" is vague and confusing.

Lines 1-4 of the instant claim recites the limitation wherein determining a first physicochemical property requires using a second physicochemical property and also recites that the limitation wherein determining a first physicochemical property requires a dependency on a third, undetermined physicochemical property. However, there is no recitation of a link between the two limitations, and it is unclear as to whether one or both of the relationships are being claimed. Specifically, if both limitations are claimed, how do the requirements of a first physicochemical property requiring both using a second physicochemical property and depending on a third physicochemical property relate to determining the first physicochemical property?

Lines 1-7 of the instant claim recite the limitation wherein both the first physicochemical property and the second physicochemical property are dependent on a third, undetermined physicochemical property. The specification does not provide a definition for the dependency and it is unclear as to how the first and second properties are each dependent on the third property, and how the dependencies relate to determining the first physicochemical property (line 1).

Lines 1-7 of the instant claim recite the limitation wherein the first physicochemical property is dependent on the composition of the respective compound, but that the second physicochemical property is not dependent on the composition of the respective compound. The specification does not provide a definition for the

dependencies and it is unclear as to how the dependencies relate to determining the first physicochemical property (line 1).

7. In claim 1, lines 8 and 10, the phrase "certain conditions" are vague and indefinite. The specification does not define the phrase and it is unclear what type of conditions are being claimed. Are the conditions physical, chemical, physicochemical, mechanical, electrical, biological, or another type of condition?

8. In claim 1, lines 8-9, the term "value" is vague and indefinite. The specification does not provide a definition for the term and it is unclear as to what type of value is being claimed.

9. In claim 1, lines 9-10 and line 12, the phrases "a second value for said second physicochemical property" and "second values", respectively are vague and indefinite. The phrases imply that there should be a first value for said second physicochemical property. However, there is no mention of a first value for said second physicochemical property. It is therefore unclear as to whether the instant phrases refer a second value that comes after a first value of the second physicochemical property, or if the term "second value" simply refers to a second measurement after the "first value" (line 8).

10. In claim 1, line 12, the phrase "using said first and second values" is vague and indefinite. The specification does not define the phrase and it is unclear as to how the first and second values are being used.

11. In claim 19, lines 2 and 3, the terms "a compound" and "the compound", respectively, are vague and indefinite. Since the parent claim (claim 1) recites "at least two compounds" (lines 1-2), it is unclear as to which compound the instant terms refer to.

12. In claim 21, lines 2 and 4, the phrase "said immobilized compound" is vague and indefinite. Since the parent claim (claim 20) recites "at least two compounds" (line 1), it is unclear as to which compound the instant phrase refers to.

13. In claim 28, lines 2-3, the phrase "using their second affinity constant of binding to a second target" is vague and indefinite. The specification does not define the instant phrase and it is unclear as to how the second affinity constant is used for "ranking at least two compounds" (line 1).

14. In claim 28, lines 12-13 and line 15, the phrases "measuring a second value for said second affinity constant" and "second values", respectively are vague and indefinite. The phrases imply that there should be a first value for said second affinity constant. However, there is no mention of a first value for said second affinity constant.

It is therefore unclear as to whether the instant phrases refer a second value that comes after a first value of the second affinity constant, or if the term "second value" simply refers to a second measurement after the "first value" (line 10).

15. In claim 28, lines 4-9, the phrase "wherein determination of said first affinity constant...for each compound comprising the steps of" is vague and indefinite.

Lines 4-6 recite the limitation wherein the first affinity constant depends on the concentration of each of said compounds and depends on the composition of the respective compound. However, the specification does not define how the first affinity constant is dependent on the concentration and composition of the compounds, and it is unclear as to what type of dependency is being claimed. Is the dependency physical, chemical, biological, or another type of dependency?

Lines 7-9 recite the limitation where said second affinity constant depends on said concentration but does not depend on the composition of the respective compound. However, the specification does not define how the second affinity constant is dependent on the concentration but not dependent on the composition of the compounds, and it is unclear as to what type of dependency is being claimed. Is the dependency physical, chemical, biological, or another type of dependency?

16. In claim 28, lines 10 and 12, the term "value" is vague and indefinite. The instant term is not defined by the specification and it is unclear as to what type of value is being

claimed. How does the value relate to the first and second "affinity constant" (lines 10 and 12)?

17. In claim 28, line 15, the phrase "using said first and second values" is vague and indefinite. The specification does not define the instant phrase and it is unclear as to how the first and second values are being used and how it relates to the "ranking" of "at least two compounds" (line 1).

18. In claim 37, line 2, the term "a compound" is vague and indefinite. Since the parent claim (claim 33) recites "at least two compounds" (lines 1-2), it is unclear as to which compound the instant term refers to.

19. In claim 39, lines 2 and 4, the phrase "said immobilized compound" is vague and indefinite. Since the parent claim (claim 38) recites "at least two compounds" (line 1), it is unclear as to which compound the instant phrase refers to.

20. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the third property, in which both the first and second properties are dependent upon, relates to the method of determining the first physicochemical property. The steps a), b), and b) in lines 8-12 of the instant claim are directed to measuring values of the first and second properties, and then

determining the first property. However, there is no mention of how the dependency of the third property affects the measuring or determining steps.

21. Claim 1 recites the limitation "the composition of the respective compound" in lines 4 and 6. There is insufficient antecedent basis for this limitation in the claim. Lines 1-2 of the instant claim recite "two compounds". However, there is no recitation of a composition associated with said compounds that would provide antecedent basis for the instant limitation.

22. Claim 1 recites the limitation "determination of said second property" in line 5. There is insufficient antecedent basis for this limitation in the claim. Previous lines to the instant limitation of the instant claims fail to recite a determination of said second property.

23. Claim 1 recites the limitation "second value" in lines 9 and 12. There is insufficient antecedent basis for this limitation in the claim. Since a first value for the second physicochemical property is not claimed, there is no antecedent basis for a "second value".

24. Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: how the concentration, in which

both the first and second affinity constants are dependent upon, relates to the method of determining the ranking at least two compounds relative to each other with respect to their first affinity constant. The steps a), b), and b) in lines 10-15 of the instant claim are directed to measuring values of the first and second values for first and second affinity constants, respectively, and then determining the first affinity constant of each compound relative to the other compounds. However, there is no mention of how the dependency of the concentration affects the measuring or determining steps.

25. Claim 28 recites the limitation "the respective compound" in lines 6 and 9. There is insufficient antecedent basis for this limitation in the claim.

26. Claim 28 recites the limitation "second value" in lines 12 and 15. There is insufficient antecedent basis for this limitation in the claim. Since a first value for the second affinity constant is not claimed, there is no antecedent basis for a "second value".

Claim Rejections - 35 USC § 103

27. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

28. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

29. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

30. Claims 1-5, 9, 15, 20-22, 28-29, 33, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 5,143,852) in view of Hardman et al (US 5,958,708).

In the instant claims, Valkirs et al reference teaches a competitive ligand-receptor assay process with antibodies (i.e. compound) that bind to a target ligand (i.e. first target) and a ligand analogue conjugate (i.e. second target) and determining the ratio of

the affinity constants for antibody binding to ligand analogue conjugate and to ligand using two binding reactions at equilibrium (i.e. measuring a first value and simultaneously measuring a second value), wherein the two binding reactions (K_L and K_{LAC}) are dependent on the concentrations of the antibody LAA (i.e. compound). See column 4, line 53 to column 6, line 20.

However, Valkirs et al reference fails to teach two compounds and the step of determining said first affinity constant for each compound relative to the other compound(s) by using said first and second values.

Hardman et al reference teaches comparing the antigen-binding affinity of a created reshaped human antibody with that of murine CDR-donor antibody TES-C21, in order to perform modifications on a 'trial and error' basis to produce reshaped human antibodies directed against human IgE having an antigen binding affinity that equals or exceeds that of the murine CDR-donor antibody. See column 3, lines 31-35 and column 4, lines 41-61.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Valkirs et al with the step of comparing the antigen-binding affinity of a created reshaped human antibody with that of murine CDR-donor antibody TES-C21, as taught by Hardman et al, in order to perform modifications on a 'trial and error' basis to produce reshaped human antibodies directed against human IgE having an antigen binding affinity that equals or exceeds that of the murine CDR-donor antibody. One of ordinary skill in the art at the time of the invention would have had reasonable expectation of success in comparing the binding affinities of two

antibodies, as taught by Hardman et al, in the method of Valkirs et al, since Valkirs et al teach the step of determining the binding affinity between an antibody and an antigen, and the method of Hardman et al teaches comparing two antibodies through binding affinities between the antibodies and an antigen.

With regards to claim 2-3, 5, and 9, Valkirs et al reference teaches affinity constants for binding reactions K_L (i.e. affinity constant; first property) and K_{LAC} (affinity constant; second property) dependent on concentrations (i.e. concentration; third property) of the antibody LAA (i.e. compound), and a target ligand (i.e. first target), as stated above. See column 4, line 53 to column 6, line 20.

With regards to claims 4 and 29, Hardman et al reference teaches both a reshaped human antibody and a murine CDR-donor antibody TES-C21 (i.e. domains of different antibodies) directed against human IgE (i.e. antigen), as stated above. See column 3, lines 31-35 and column 4, lines 41-61.

With regards to claims 15 and 33, Valkirs et al reference teaches that the ligand analogue antibody (i.e. compound) can be contacted in solution with the assay fluid. See column 7, lines 14-18.

With regards to claims 20 and 38, Valkirs et al reference teaches the immobilization of the ligand analogue antibody (i.e. compound) on a solid phase. See column 7, lines 8-14.

With regards to claim 22, Valkirs et al reference teaches binding reactions performed in equilibrium, as stated above. See column 4, line 53 to column 6, line 20.

With regards to claims 21 and 39, Valkirs et al reference teaches that assays were performed by preparing reaction mixtures in microtiter plate wells containing 40 μL of benzoylecgonine standard (i.e. first target) and 40 μL of benzolylecgonine ligand analogue conjugated to alkaline phosphatase (i.e. second target) at 100 nM (i.e. known amounts), and ratios of antibody affinity to conjugate/benzoylecgonine and ratio of antibody affinity to conjugate/benzoylecgonine ligand analogue are determined (i.e. measured). See column 14, lines 63-67 and Table 1.

31. Claims 6, 10, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 5,143,852) in view of Hardman et al (US 5,958,708) as applied to claims 1-3, 5, 9, and 28 above, and further in view of Dona (US 4,686,181).

Valkirs et al and Hardman et al references have been disclosed above, but fail to teach that the second target is a functional fragment of an antibody.

Dona reference teaches an assay with an analyte (i.e. first target), binding counterpart of the analyte (i.e. compound), and specific binding analog of the analyte (i.e. second target) that is any substance which behaves similarly to the analyte with respect to binding by a binding counterpart of the analyte, wherein the analyte can be immunoglobulins such as IgG, IgM, IgA, IgD, and IgE, and their fragments, in order to detect an immunologically-active protein for which there is a specific binding counterpart available. See column 4, lines 9-23 and 36-42.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Valkirs et al and Hardman et al with an assay with an

analyte (i.e. first target), binding counterpart of the analyte (i.e. compound), and specific binding analog of the analyte (i.e. second target) that is any substance which behaves similarly to the analyte with respect to binding by a binding counterpart of the analyte, wherein the analyte can be immunoglobulins such as IgG, IgM, IgA, IgD, and IgE, and their fragments, as taught by Dona, in order to detect an immunologically-active protein for which there is a specific binding counterpart available. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including analogues to immunoglobulin analytes, as taught by Dona, in the method of Valkirs et al and Hardman et al, since both Valkirs et al and Dona teach binding of counterparts to both analytes and analyte analogues, and both Hardman et al and Dona teach immunoglobulin analytes.

32. Claims 7-8, 13-14, and 31-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 5,143,852) in view of Hardman et al (US 5,958,708) as applied to claims 1-3 and 28 above, and further in view of Malmqvist (METHODS: A Companion to Methods in Enzymology, 1996, vol. 9, pp. 525-532).

Valkirs et al and Hardman et al references have been disclosed above, and Hardman et al reference additionally teaches that determination of affinities of the reference and the reshaped test antibody (i.e. multiple compounds) is performed under identical conditions in the same assay (i.e. preformed in parallel). See column 6, lines 43-48.

However, Valkirs et al and Hardman et al fail to teach that each compounds is contained in a defined area of a substrate or one spots in a microarray.

Malmqvist reference teaches a BIAcore 2000 instrument with four channels that have different ligands, in order to perform higher throughput and lower reagent consumption for epitope mapping. See page 531, left column, last paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Valkirs et al and Hardman et al with a BIAcore 2000 instrument with four channels that have different ligands, as taught by Malmqvist, in order to perform higher throughput and lower reagent consumption for epitope mapping. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in separating bound ligands, as taught by Malmqvist, in the method of Valkirs et al and Hardman et al, since Valkirs et al and Hardman et al teach separate determinations for affinities between an antigen and a reference or reshaped test antibody, and the four channels taught by Malmqvist provide one technique for separate affinity determinations.

33. Claims 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 5,143,852) in view of Hardman et al (US 5,958,708) as applied to claims 1-3, 5, 9, and 28 above, and further in view of Dona (US 4,686,181) as applied to claim 10 above, and further in view of Malmqvist (METHODS: A Companion to Methods in Enzymology, 1996, vol. 9, pp. 525-532).

Valkirs et al, Hardman et al, and Dona references have been disclosed above, but fail to teach that each compounds is contained in a defined area of a substrate or one spots in a microarray.

Malmqvist reference teaches a BIAcore 2000 instrument with four channels that have different ligands, in order to perform higher throughput and lower reagent consumption for epitope mapping. See page 531, left column, last paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Valkirs et al, Hardman et al, and Dona with a BIAcore 2000 instrument with four channels that have different ligands, as taught by Malmqvist, in order to perform higher throughput and lower reagent consumption for epitope mapping. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in separating bound ligands, as taught by Malmqvist, in the method of Valkirs et al, Hardman et al, and Dona, since Valkirs et al, Hardman et al, and Dona teach separate determinations for affinities between an antigen and a reference or reshaped test antibody, and the four channels taught by Malmqvist provide one technique for separate affinity determinations.

34. Claims 16-19 and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valkirs et al (US 5,143,852) in view of Hardman et al (US 5,958,708) as applied to claims 1, 15, 28, and 33 above, and further in view of Hechinger (US 6,159,748).

Valkirs et al and Hardman et al references have been disclosed above, but fail to teach that steps (a) and (b) are performed by simultaneously contacting said solution with said first and said second target, each target being immobilized on a solid phase, and wherein the amounts of compound binding to said first and second target are measured for each compound (claims 16 and 34), wherein said first and said second target are being immobilized to different subsets of microspheres (claims 17 and 35), wherein said different subsets are characterized by different fluorescent labels (claims 18 and 36), and identifying binding of a compound to said first or second subset of microspheres by binding of a fluorescence label to the compound (claims 19 and 37).

Hechinger reference teaches a bead detection system with a primary antibody (i.e. compound) bound to an antigen (i.e. target) immobilized on a latex bead carrier (i.e. microsphere) with an attached indicator system (i.e. labels) that binds to the antibody, wherein multiple beads can be coated with a different protein (i.e. first or second target), and wherein a mixture of different antigen coated beads is placed in a mixture (i.e. simultaneously contacting), in order to simultaneously detect multiple antibodies and to provide a means for detection with highly sensitive fluorescence detectors. See Figure 1; column 3, lines 33-60; and column 4, lines 2-9.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Valkirs et al and Hardman et al with a bead detection system with a primary antibody (i.e. compound) bound to an antigen (i.e. target) immobilized on a latex bead carrier (i.e. microsphere) with an attached indicator system (i.e. labels) that binds to the antibody, wherein multiple beads can be coated with a

different protein (i.e. first or second target), and wherein a mixture of different antigen coated beads is placed in a mixture (i.e. simultaneously contacting), as taught by Hechinger, in order to simultaneously detect multiple antibodies and to provide a means for detection with highly sensitive fluorescence detectors. One of ordinary skill in the art at the time of the invention would have reasonable expectation of success in including microspheres and fluorescent labels, as taught by Hechinger, in the method of Valkirs et al and Hardman et al, since Valkirs et al and Hardman et al teach binding of antibodies to multiple antigens, and fluorescently labels and microspheres taught by Hechinger is one means of performing binding of antibodies to multiple antigens.

Conclusion

35. No claims are allowed.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Leon Y Lum
Patent Examiner
Art Unit 1641

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01/17/05